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Docket No. AR03234-USA-NP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Edgren et al.

Serial No. : 10/606,575

Art Unit: 1615

Filed : June 26, 2003

Examiner:

For : METHODS AND DOSAGE FORMS FOR INCREASING SOLUBILITY  
OF DRUG COMPOSITIONS FOR CONTROLLED DELIVERY

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March 31, 2005

(Date of Deposit)

Mary A. Appollina, Reg. No. 34,087

(Name of applicant, assignee, or Registered Representative)

/Mary A. Appollina/

(Signature)

March 31, 2005

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e)  
(attached); or

☐ Please charge Deposit Account No. 10-  
0750/ / the fee of \$180.00 as set forth  
in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

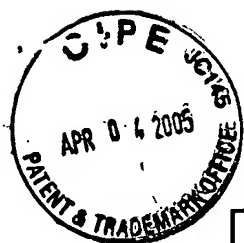
☒ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/AR03234/MAA. This form is submitted in triplicate.

Respectfully submitted,

/Mary A. Appollina/  
Mary A. Appollina  
Reg. No. 34,087  
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DATED: March 31, 2005



PTO-SB-08A (08-00)

Approved for use through 10-31-2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 7

Application Number	10/606,575
Filing Date	June 26, 2003
First Named Inventor	EDGREN et al.
Group Art Unit	1615
Examiner Name	Not yet assigned
Attorney Docket Number	AR03234

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		6,559,293	B1	ALMARSSON et al.	05-06-2003	
		2003/0072802	A1	CUTLER	04-17-2003	
		6,210,712	B1	EDGREN et al.	04-03-2001	
		6,174,547	B1	DONG et al.	01-16-2001	
		5,938,654		WONG et al.	08-17-1999	
		5,614,578		FERRARI et al.	03-25-1997	
		5,413,672		HIROTSUJI et al.	05-09-1995	
		5,391,381		WONG et al.	02-21-1995	
		5,387,700		MARYANOFF et al.	02-07-1995	
		5,340,590		WONG et al.	08-23-1994	
		5,324,280		WONG et al.	08-23-1994	
		5,252,338		JAO et al.	10-12-1993	
		5,190,765		JAO et al.	03-02-1993	
		5,160,743		EDGREN et al.	11-03-1992	
		5,156,850		WONG et al.	10-20-1992	
		5,110,597		WONG et al.	05-05-1992	
		5,082,655		AGARWALA et al.	01-21-1992	
		5,024,842		EDGREN et al.	06-18-1991	
		5,023,088		WONG et al.	06-11-1991	
		5,019,397		WONG et al.	05-28-1991	
		5,006,346		EDGREN et al.	04-09-1991	

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 7

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		Number	Kind Code <sup>2</sup> (if known)			
		4,961,932		THEEUWES	10-09-1990	
		4,957,494		WONG et al.	09-18-1990	
		4,940,465		THEEUWES et al.	07-10-1990	
		4,931,285		EDGREN et al.	06-05-1990	
		4,915,949		WONG et al.	04-10-1990	
		4,892,778		THEEUWES et al.	01-09-1990	
		4,853,229		THEEUWES et al.	08-01-1989	
		4,824,675		WONG et al.	04-25-1989	
		4,681,583		URQUHART et al.	07-21-1987	
		4,578,075		URQUHART et al.	03-07-1978	
		4,519,801		EDGREN	05-28-1985	
		4,513,006		MARYANOFF et al.	04-23-1985	
		4,327,725		CORTESE et al.	05-04-1982	
		4,207,893		MICHAELS	06-17-1980	
		4,160,020		AYER et al.	07-03-1979	
		4,111,202		THEEUWES	09-05-1978	
		4,111,201		THEEUWES	09-05-1978	
		4,088,864		THEEUWES	05-09-1978	
		4,077,407		THEEUWES et al.	03-07-1978	
		4,008,719		THEEUWES et al.	02-22-1977	
		4,002,173		MANNING et al.	01-11-1977	
		3,995,631		HIGUCHI	12-07-1976	

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Sheet 3 of 7

Application Number	10/606,575
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		Number	Kind Code <sup>2</sup> (if known)			
		3,916,899		THEEUWES et al.	11-04-1975	
		3,865,108		HARTOP	02-11-1975	
		3,845,770		THEEUWES et al.	11-05-1974	
		3,546,142		MICHAELS et al.	12-08-1970	
		3,541,006		BIXLER et al.	11-17-1970	
		3,541,005		STRATHMANN et al.	11-17-1970	
		3,276,586		ROSEAN	10-04-1966	
		3,173,876		JACKSON	03-16-1965	
		3,133,132		LOEB et al.	05-12-1964	
		2,799,241		WURSTER	07-16-1957	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		WO	00/72841		Jeffrey Berlant	12-07-2000		
		WO	00/48607	A	Tovama Farmaceutvskih et al.	08-24-2000		
		WO	00/25790	A	ALZA Corporation	05-11-2000		
		WO	99/62496	A1	ALZA Corporation	12-09-1999		
		WO	99/44581	A2	Ortho-McNeil Pharmaceutical, Inc.	09-10-1999		
		WO	98/14168	A2	ALZA Corporation	04-09-1998		
		WO	98/06380	A2	ALZA Corporation	02-19-1998		

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 4 of 7

Application Number	10/606,575
Filing Date	06/26/2003
First Named Inventor	EDGREN et al.
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## U.S. PATENT DOCUMENTS

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		Number	Kind Code <sup>2</sup> (if known)			
		6,248,363		PATEL et al.	06-19-2001	
		6,569,463		PATEL et al.	05-27-2003	
		2001/0012847	A1	LAM et al.	09-09-2001	
		6,294,192		PATEL et al.	09-25-2001	
		5,906,832		JAO et al.	05-25-1999	
		5,633,011		DONG et al.	05-27-1997	
		5,620,705		DONG et al.	04-15-1997	
		5,262,171		LOGIN et al.	11-16-1993	
		2002/0044960	A1	CHERUKURI	04-18-2002	
		2002/0044962	A1	CHERUKURI et al.	04-18-2002	
		2002/0127196	A1	AVILA et al.	09-12-2002	

## FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		WO	01/37808		PATEL et al.	05-31-2001		
		WO	01/12155		PATEL et al.	02-22-2001		
		WO	98/23263		HOMEL et al.	06-04-1998		
		WO	00/00179		BEOM et al.	01-06-2000		
		WO	99/63971		TALLAUAKHALA	12-16-1999		
		WO	95/06460		ALZA CORPORATION	03-09-1995		
		WO	04/010970	A1	JAO et al.	02-05-2004		

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**INFORMATION DISCLOSURE  
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Sheet 5 of 7

Application Number	10/606,575
Filing Date	06/26/2003
First Named Inventor	EDGREN et al.
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	AR03234

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		2003/0185882	A1	VERGEZ et al.	10-02-2003	
		2003/0228358	A1	PERLMAN et al.	12-11-2003	
		2004/115262	A1	JAO et al.	06-17-2004	
		2002/0022245	A1	HEBEBRAND et al.	02-21-2002	
		2003/0021841	A1	MATHARU et al.	01-30-2003	
		2004/0053894	A1	MAZESS et al.	03-18-2004	
		4,888,168		POTTS et al.	12-19-1989	
		5,082,655		SNIPES et al.	01-21-1992	
		5,817,321		ALAKHOV et al.	10-06-1998	
		6,562,375	B1	SAKO et al.	05-13-2003	
		2005/0053653	A1	KIDANE et al.	03-10-2005	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
		WO	02/44276	A2	AVILA et al.	06-06-2002		
		WO	03/002151	A1	MASSIRONI	01-09-2003		
		WO	03/004009	A1	MATHARU et al.	01-16-2003		
		WO	03/011204	A2	CHERUKURI	02-13-2003		
		WO	03/011205	A2	CHERUKURI et al.	02-13-2003		
		WO	03/039519	A2	VERGEZ et al.	05-15-2003		
		WO	03/063833	A1	PERLMAN et al.	08-07-2003		

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Considered

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 7

Application Number	10/606,575
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<i>Filing Date</i>	06/26/2003
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<i>First Named Inventor</i>	EDGREN et al.
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Group Art Unit	1615
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Examiner Name

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## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

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Sheet 7 of 7

<b>Application Number</b>	10/606,575
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<b>Examiner Name</b>	Not yet assigned
<b>Attorney Docket Number</b>	AR03234

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
		Encyclopedia of Polymer Science and Technology, "Cellulose Esters, Organic," 3:325-354, Interscience Publishers, NY, 1964	
		Klaus Florey Ed., <u>Analytical Profiles of Drug Substances</u> , 13:425, Academic Press, New York, 1984.	
		BASF Technical Bulletin "PLURONIC® and PLURONIC® R Block Copolymer Surfactants" BASF Corporation, 1998-2003.	
		BASF Technical Bulletin "TETRONIC® and TETRONIC® R Block Copolymer Surfactants" BASF Corporation, 1998-2003.	
		Scott & Roff, <u>Handbook of Common Polymers</u> , CRC Press., Cleveland Ohio, 1971.	
		Larry Hixon, et al., "Sizing Materials by Crushing and Grinding", <u>Chemical Engineering</u> , 94-103, November 1990.	
		Eugene L. Parrott, "Milling of Pharmaceutical Solids", <u>Journal of Pharmaceutical Sciences</u> , 61(6):813-829, 1974.	
		Perry's Chemical Engineers Handbook, Perry, Green & Maloney Editors, et al, 6 <sup>th</sup> Ed., "Introduction to Screening and Wet Classification", pp. 21.13 to 21.19, 1984..	
		Remington's Pharamaceutical Sciences, 18 <sup>th</sup> Ed, Ch 91, "Sustained-Release Drug Delivery Systems: Oral Dosage Forms" pp.1682-1685, 1990.	
		Remington's Pharamaceutical Sciences, 17 <sup>th</sup> Ed, Ch. 89, "Powders," pp. 1585-1594, 1985.	
		Physician's Desk Reference, Medical Economics-Thompson Healthcare, 56 <sup>th</sup> Ed., "TOPAMAX®," pp. 2590-2595 and "Dilantin-125"p. 2626, 2002.	
		Giancarlo Santus & Richard W. Baker, "Osmotic drug delivery: a review of the patent literature," <u>Journal of Controlled Release</u> , 35:1-21, 1995.	
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



## SUBMISSION UNDER MPEP 609 D

Page 1 of 1

Application Number	10/606,575
Filing Date	June 26, 2003
First Named Inventor	EDGREN et al.
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	AR03234-USA-NP

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	
		D. Edgren et al.	USSN 10/606575		
		I. Reyes et al.	USSN 10/910,040		
		N. Yam et al.	USSN 10/920,934		
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		D. Edgren et al.	USSN 11/024,329		
		D. Edgren et al.	USSN 11/024,330		
		D. Edgren et al.	USSN 11/024,378		

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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